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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/377,795	08/20/1999	MICHAEL KARIN	P-UD-3613	8313

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EXAMINER	
VIVLEMORE, TRACY ANN	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/377,795	KARIN ET AL.	
	Examiner	Art Unit	
	Tracy Vivlemore	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *14 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,13-15 and 30-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *13-15* is/are allowed.

6)☒ Claim(s) *11 and 30-35 and 38-40* is/are rejected.

7)☒ Claim(s) *36 and 37* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 14, 2006 has been entered.

Claim Objections

Claim 30 is objected to because of the following informalities: this claim is ungrammatical because it appears to be missing the word "of" between the words "1408" and "SEQ". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 30 has been amended to add the phrase "in its entirety". The metes and bounds of this claim cannot be determined because it is unknown what component of the claim this phrase is meant to refer to. It is unknown if it is meant to define that the antisense polynucleotide is complementary to the entirety of nucleotides 149-1408 of SEQ ID NO: 1 or if the antisense polynucleotide can be a shorter sequence that is entirely complementary to some portion of nucleotides 149-1408 of SEQ ID NO: 1, such as a 20 base pair long oligonucleotide that is complementary to 20 nucleotides within nucleotides 149-1408. Amending the claim to recite an antisense polynucleotide "comprising the nucleotide sequence complementary to nucleotides 149-1408" would be remedial.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 31-35 and 38-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 11 is directed to a human IKK-γ nucleic acid that encodes a polypeptide having at least 90% amino acid identity with SEQ ID NO: 2 that has a binding activity of the full length IKK-γ polypeptide. Claims 31-34 define the binding activities as being interaction with IKK-α/β in cells, IKK-β binding, IKK-α binding, and dimerization or trimerization activity. Claim 35 is directed to nucleic acids that encode an IKK-γ deletion derivative that has a binding activity of the full length IKK-γ polypeptide. Claims 38-40 are directed to nucleic acids that encode polypeptides having 95%, 97% or 99% amino acid identity to SEQ ID NO: 2.

Nucleic acids that encode peptides having at least 90% amino acid identity to SEQ ID NO: 2 constitute a large genus of compounds and include sequences where the region of non-identity occurs in one area of the sequence and sequences where the area of non-identity is interspersed throughout the sequence in either a regular or random fashion. These polypeptides may have amino acid sequences quite different from that of SEQ ID NO: 2.

The instant specification describes the isolation of IKK-γ and describes that binding activities of IKK-γ include binding of IKK-α, binding of IKK-β, interaction with IKK-α/β in cells and dimerization or trimerization. The specification further describes the structure of fragments of IKK-γ having either C- or N-terminal deletions. These two fragments are described as retaining each of the binding activities of full-length IKK-γ and thus do not provide a disclosure of any structures essential for the function of having a binding activity of IKK-γ. The specification does not describe nor is it known in

the prior art what amino acids constitute the critical residues of IKK-γ that produce the function of binding IKK-α or IKK-β, interacting with IKK-α/β in cells or dimerization/trimerization activity such that the skilled artisan could envision which amino acids can be altered and still produce a structure that retains the recited biological functions of IKK-γ. For example, if the structure of one or more domains or motifs present in SEQ ID NO: 2 is known to be responsible for the function of IKK-β binding activity, the skilled artisan would be able to readily ascertain the structures of nucleic acids that encode a polypeptide 90% identical to SEQ ID NO: 2 and retain the function of binding IKK-β. Absent such knowledge, the genus of compounds that have both 90% identity to SEQ ID NO: 2 and a biological function of IKK-γ is not adequately described.

Claim 35 encompasses deletion derivatives of IKK-γ that retain binding activity. The specification exemplifies two deletion derivatives, each of which retains all binding activities of IKK-γ. The specification does not describe how many amino acids could be deleted from a derivative and have the resultant polypeptide retain a binding activity of full-length IKK-γ. The two species of deletion derivatives disclosed in the specification are not representative of the genus of deletion derivatives having the binding activities of IKK-γ because the structures of these species would not lead the skilled artisan to recognize what portions of IKK-γ can be deleted and retain binding activity.

Claims 38-40 are directed to nucleic acids that encode polypeptides having amino acid identities with SEQ ID NO: 2 ranging from 95% to 99%. The nucleic acids

encompassed by the claims include those having functions different from those disclosed as being characteristic of IKK-γ and include nucleic acids encoding polypeptides having no function at all. The specification provides no description of any nucleic acids that encode polypeptides having the claimed identity with SEQ ID NO: 2 and having any function.

In order for the written description provision of 35 USC 112, first paragraph to be satisfied, applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed. For example, MPEP 2163 states in part,

> "An adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004) (The patent at issue claimed a method of selectively inhibiting PGHS-2 activity by administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product, however the patent did not disclose any compounds that can be used in the claimed methods. While there was a description of assays for screening compounds to identify those that inhibit the expression or activity of the PGHS-2 gene product, there was no disclosure of which peptides, polynucleotides, and small organic molecules selectively inhibit PGHS-2. The court held that "[w]ithout such disclosure, the claimed methods cannot be said to have been described.")."

The skilled artisan cannot envision the detailed structure of the encompassed nucleic acids that will encode a polypeptide that is 90% identical to SEQ ID NO: 2 that additionally retains a biological function of the full-length IKK-g, regardless of the complexity or simplicity of the method of isolation.

Therefore, the full breadth of the nucleic acids encompassed by the claims do not meet the written description provision of 35 USC 112, first paragraph. The species

specifically disclosed are not representative of the genus because the genus is highly variant.

Response to arguments Claim Rejections - 35 USC § 112

In the remarks April 14, 2006, applicants contend that one skilled in the art would recognize applicants are in possession of the claimed invention when knowledge of the art is combined with the correlations between function and structure provided in the specification. Applicants point to teachings within the specification that the polypeptide disclosed as SEQ ID NO: 2 contains coiled-coil and leucine zipper regions, which indicate that IKK-γ can be engaged in homotypic and heterotypic interactions. Applicants further point to figure 2 where IKK-γ is contemplated as having four α-helical regions, including a leucine zipper and to the disclosure of deletion derivatives that retain binding activity. These arguments are not persuasive because they merely recite structural features that are contemplated as existing in the polypeptide but do not describe a correlation between these structures and function of sharing binding activity with full-length IKK-γ. The disclosure that IKK-γ comprises coiled-coil and leucine zipper regions does not provide a correlation of which of these regions is required for binding activity. Additionally, the disclosure of deletion derivatives that retain all binding activities of full-length IKK-γ also does not point to exactly what portion of IKK-γ is essential to the binding activity of the full-length polypeptide such that the skilled artisan would recognize what portions of SEQ ID NO: 2 can be deleted and retain binding activity of full-length IKK-γ.

Allowable Subject Matter

Claims 13-15, 30, 36 and 37 are free of the prior art searched.

Claims 36 and 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The central FAX Number is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore
Examiner
Art Unit 1635

TV
June 22, 2006

JANE ZARA, PH.D.
PRIMARY EXAMINER

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